K070311

510(k) SUMMARY of Safety and Effectiveness

(In accordance with SMDA of 1990 and pursuant with 21 CFR 807.92) APR 24 2007

I. Applicant Information:

Date Prepared: April 6, 2007
Submitter: Medtronic, Inc.

Address: 710 Medtronic Parkway, NE
Minneapolis, MN 55432-5604

Establishment
Registration No. 2135394

Contact Person: Debbie Kidder.
Senior Regulatory Affairs Specialist

Telephone Number: (763) 391-9251
Fax Number: (763) 391-9279

II. Device Information:

Trade Name: Cardioblate® Gemini™ Surgical Ablation Device, Model 49260 and Model 49261

Common Name: Cardioblate® Surgical Ablation System, which consists of: Cardioblate® 68000 Generator (K060400) and the following devices:

- Cardioblate® BP2 Surgical Ablation Device, Model 60831 (K060400)
- Cardioblate® LP Surgical Ablation Device, Model 60841 (K060400)
- Cardioblate® Monopolar Pen, Model 60813 and Model 60814 (K013392)

Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Classification: Class II, 21 CFR 878.4400
Product Code: GEI

Predicate Device: Cardioblate® LP Model 60841 and BP2 Model 60831 Surgical Ablation Device, (K060400), Reg. No. 878.4400; Product Code: GEI

Predicate Device Intended Use: The Medtronic Cardioblate® System is intended to ablate soft tissue during general surgery using radiofrequency energy.

Predicate Device: Guidant FLEX 10 Probe Accessory, (K013946), Reg. No. 878.4400; Product Code: NYE

Predicate Device Intended Use: The FLEX 10 Accessory is indicated for surgical ablation of soft tissue, in addition to striated, cardiac and smooth muscle by induction of thermal necrosis in the targeted tissue. The system is a device indicated for use under direct visualization, in surgical procedures, including minimally invasive cardiac surgery procedures. The probes ablate the target tissue by creating an inflammatory response, or thermal necrosis.

Device Description: The Medtronic Cardioblate® Gemini™ Surgical Ablation Device is a hand held, bipolar radiofrequency ablation device intended to ablate soft tissue during general surgery. It has a saline irrigation system to deliver fluid at the contact point between the tissue and electrode to cool the tissue during radiofrequency energy delivery. Two unique jaw curvatures are provided: a standard curve (Model 49260) and extra curve (Model 49261). This device is intended for intermittent operation. Sterile, Nonpyrogenic, Disposable, Single use only.

Intended Use: The Cardioblate Gemini Surgical Ablation Device is intended to ablate soft tissue during general surgery using radiofrequency energy. The system is indicated for use under direct or endoscopic visualization, in surgical procedures, including minimally invasive surgical procedures.

Contraindications: The Cardioblate® Surgical Ablation System is contraindicated for patients that have active endocarditis at the time of surgery.

Ablation in a pool of blood (eg, through a purse string suture on a beating heart). Effects of this type of ablation have not been studied.

III. SUBSTANTIAL EQUIVALENCE TESTING SUMMARY

The Cardioblate® Gemini™ Surgical Ablation Device has demonstrated substantial equivalence to the predicate devices based on the indications for use, basic overall function and performance characteristics. The Cardioblate® Gemini™ Surgical Ablation Device has been tested and is considered safe and effective per the following recognized consensus standard AAMI/ANSI HF18:2001, Electrosurgical Devices, IEC 60601-1, and IEC 60601-2-2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

APR 24 2007

Re: K070311
Trade/Device Name: Medtronic Cardioblate® Gemini™ Surgical Ablation Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 9, 2007
Received: April 10, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K070311

Device Name: Medtronic Cardioblate® Gemini™ Surgical Ablation Device

Indications for use:

The Cardioblate Gemini Surgical Ablation Device is intended to ablate soft tissue during general surgery using radiofrequency energy. The system is indicated for use, under direct or endoscopic visualization, in surgical procedures, including minimally invasive surgical procedures.

Prescription Use x **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070311